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Orientation Handbook for Members of Research Grants Science Review Panels

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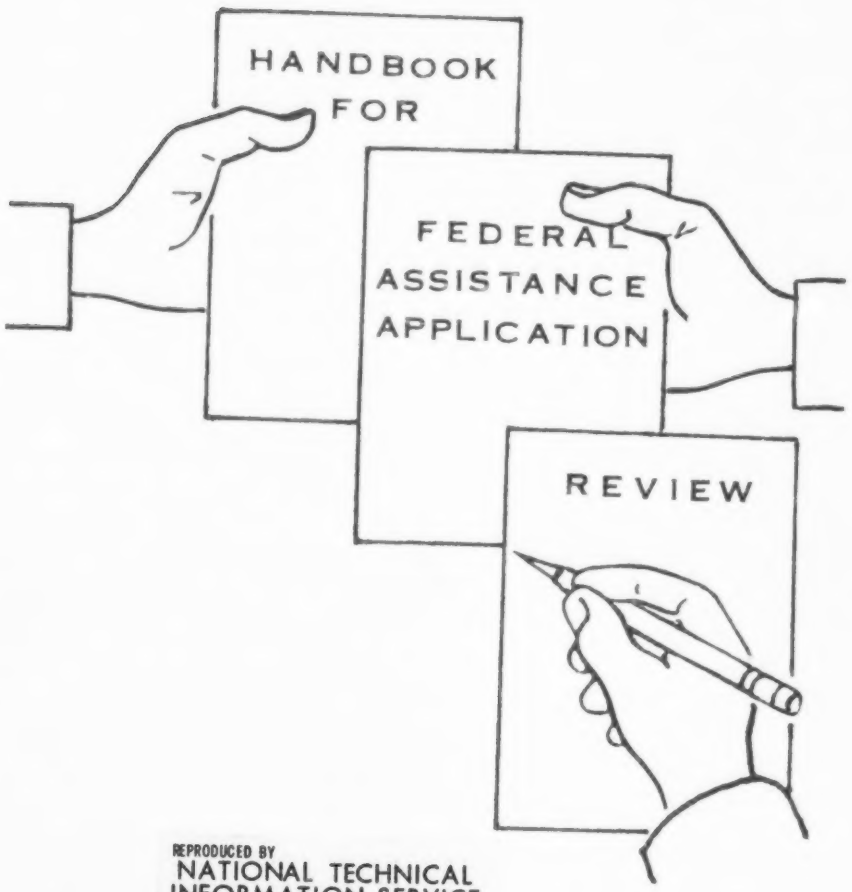

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16. ABSTRACT

The mission of the U. S. Environmental Protection Agency is to protect the Nation's land, air, and water systems. The Office of Research and Development is the principal scientific component of the Agency with the primary function to obtain credible scientific information on which to base sound national policy for pollution control.

This handbook describes the structure, functions, and operational procedures of the Science Review Panels used by the Agency for the peer review of research grant applications.

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Introduction

The mission of the U.S. Environmental Protection Agency (EPA) is to protect the Nation's land, air, and water systems. The Office of Research and Development (ORD) is the principal scientific component of the Agency with the primary function to obtain credible scientific information on which to base sound national policy for pollution control.

The Research Grants Program of the Office of Exploratory Research is the unit within ORD that has the primary responsibility for all research grant applications received by EPA, including their scientific evaluation and the subsequent administration and monitoring of those awarded grants. The research grants supported are investigator-initiated and deal with basic or fundamental research projects.

This Handbook describes the structure, functions, and operational procedures of the Science Review Panels used by the Agency for the peer review of research grant applications.

Science Review Panels

Structure/Membership

Science Review Panels are established for each of the following principal areas of interest to the research program of the Agency:

- Environmental Biology
- Environmental Chemistry, Physics, and Measurements—Air
- Environmental Chemistry, Physics, and Measurements—Water
- Environmental Engineering
- Environmental Health.

Each Science Review Panel is operated through a cooperative agreement between the Agency and a non-EPA employee who serves as the Chair of the Panel. The Chair is selected for a period of three years by the Assistant Administrator for Research and Development. The Chair is responsible for conducting the scientific review of applications assigned to the Panel, and for providing the Agency with a Summary Statement of the review and recommendations made by the Panel for each application.

Each Panel is composed primarily of non-EPA scientists who are acknowledged experts in their respective disciplines. The invitation to become a member of a Panel is extended by the Panel Chair with the approval of the EPA. Additionally, every effort is made to have representative geographic distribution and minority group representation on the Panels' memberships.

A Science Review Administrator (SRA), who is a Research Grants Program staff person, is an ex-officio member of a Panel. The SRA provides

policy and procedural guidance, and assists the Chair in the preparation and conduct of the Panel meetings. Because of the diversity of the applications received and the disciplines required for their scientific review, in some cases a Panel may establish sub-Panels. The sub-Panels are organized around categories of identifiable areas of research.

Function

It is the responsibility of each Panel to review and evaluate the scientific quality of the applications assigned to it, and to provide the Agency with a critique regarding the scientific merit along with a recommendation of an appropriate funding level for each application reviewed. The Panels focus attention on the scientific merits of proposals.

Review Process

Assignments

Grant applications are received by the Agency's Grants Administration Division where they are reviewed to determine their legal and administrative acceptability. The applications are forwarded to the Research Grants Program for appropriate Panel assignment.

The Panel Chair, who may be assisted by the SRA, makes primary review assignments to appropriate Panel members. Each application is assigned to at least three primary reviewers who independently are responsible for providing a scientific review and evaluation. If a reviewer believes an application has been inappropriately assigned the Chair should be immediately notified. Each primary reviewer receives from the SRA a full copy of each application assigned, along with any appropriate background material. Every effort is made to limit the number of primary assignments to 5 per Panelist, with an interval of no less than 5 weeks between the time of assignment and the Panel meeting. In addition, copies of the cover sheet and abstracts for all applications to be considered by the Panel are provided to each member before the Panel meeting. A complete copy of any application not assigned to a Panelist may be requested from the SRA. Complete copies of all applications to be reviewed are available at the Panel meeting.

Before making the primary review assignments, the Panel Chair or SRA will contact each Panelist regarding their availability at the forthcoming scheduled review meeting. It is imperative for the Panelists to respond promptly so that assignments can be properly and efficiently made. A Panelist may not be assigned applications for a given meeting because either their services are not required due to the mix and/or number of applications to be reviewed, or the Panelist has an application scheduled for review at that meeting. In the case of the latter, the Research Grants Program policy prohibits the participation of a Panelist at a meeting at which their application is to be reviewed.

Primary Reviewers' Written Evaluation

The primary reviewers' evaluations are to be prepared in writing before the scheduled Panel meeting. These evaluations are to follow the Guidelines

for Reviewers' Written Evaluation (Appendix A) and include the following criteria:

- Quality of research plan (including theoretical and/or experimental design, originality, and creativity)
- Qualifications of principal investigator and staff including knowledge of subject area
- Potential contribution to scientific knowledge
- Availability and adequacy of facilities and equipment
- Budgetary justification.

The written reviews along with discussion notes from the Panel meeting serve as the basis for the preparation of the Summary Statement.

Meetings

Panels ordinarily meet for application reviews two or three times each fiscal year, usually for 2 days at a time. The frequency depends upon the number of applications and availability of grant funds. Meeting locations are selected by the Panel Chair with the approval of the SRA and are generally determined during a Panel meeting executive/administrative session. At least one meeting each fiscal year is at the location of an EPA research laboratory considered appropriate to a given Panel.

The SRA prepares a list of the applications to be reviewed for each Panel meeting. The review of each application begins with the evaluations and recommendations of the primary reviewers. This is followed by Panel discussion until, by consensus, there is sufficient information from which a considered scientific appraisal and recommendation for funding can be made.

Recommendations by Reviewers and Panel

The reviewers, and ultimately the Panel, will recommend a research grant application for approval, disapproval, or deferral based on the scientific merit of the proposal.

Approval: Based on the review criteria, the proposal has sufficient merit to be worthy of support. (A recommendation of approval indicates that an award be made provided that sufficient funds are available.) The recommendation can be for the time and amount requested or for an adjusted time and/or amount. A numerical priority score is required.

Disapproval: The application does not have sufficient merit to be worthy of support. No priority score is required.

Deferral: This recommendation may be made *only* if sufficient information is not available from the review to arrive at a satisfactory consensus of approval or disapproval. Deferral applications are reviewed again at the next Panel meeting after the additional information is obtained either by submission from the applicant or by a site visit. A deferral recommendation will not be used as a mechanism to allow the applicant to improve or redirect the proposal.

When a consensus is reached with two or more Panelists not in agreement, a "minority report" must be prepared, identified, and included in

the Summary Statement. After a consensus has been reached on an application, each panelist independently and privately records a numerical priority score that reflects the level of scientific merit of the application. The Panels use either a 100 point or 10 point system, with 0 the least meritorious and 100, or 10 the most meritorious.

Site Visits

A project site visit is recommended only when additional information is needed that cannot be communicated satisfactorily through correspondence or by telephone. Usually such information relates to specific details about the scientific aspects of the proposal; the arrangements for collaboration; the progress during a previous project period; or the departmental or institutional interest, commitment, support, or plans in relation to the personnel and the project. In some cases, the Panel may need to observe an experimental technique or methodology or assess the appropriateness of special equipment and procedures that are essential to the conduct of the proposed research. The site visit team customarily includes a small number of Panelists and an SRA. In some cases, the team may include ad hoc consultants with special competence in some unique, critical aspects of the proposed investigation. A site visit report is prepared by the site team Chair and submitted to the SRA and Panel's Chair for discussion at the next review meeting.

Research Material

Research that involves the use of human subjects or material or data derived from humans, laboratory animals, and/or the use of hazardous materials (including recombinant DNA) requires special attention. Such studies must be carried out in compliance with EPA policy which in general conforms to the policy and guidelines established by NIH. (See Appendix B.)

Other Panel Duties

In addition to reviewing grant applications, Panels may be asked to survey and evaluate the status of research in their fields and to identify research areas that should be initiated, strengthened, or expanded. Panel recommendations may be sought to identify neglected areas of research, research needs such as critical shortages of research resources, and ways to improve the quality of review.

Review-Related Issues

Conflict of Interest

When a member of a Panel or a close relative, friend, or close professional associate of a Panel member is named as an investigator in a grant application, the Panel member will not be involved in or privy to the review of the application, and will be excused from the review of such applications. Panel members also will be absent from the meeting when applications submitted by their own institution are being discussed.

It is often difficult for the Chair or SRA to determine whether there is a conflict of interest that requires a Panel member to be excused from a particular review. Therefore, it is the responsibility of the member to notify the Chair or the SRA in advance. Each Panelist will be required to submit a signed No Conflict of Interest Form (Appendix C) at each meeting.

Confidentiality

Grant applications, review materials, and proceedings of Panel meetings are considered confidential by Panelists and EPA staff. All applications and review materials will be left with the SRA at the conclusion of a review meeting or a site visit.

It is particularly important that applicants receive no premature information regarding the status of their proposals. Such disclosures can result in misinterpretation and represent a serious abuse of the privileged nature of the peer review procedure. The protection of the confidentiality of review proceedings is essential to maintaining a peer review system that will enable EPA to allocate public funds for research effectively and impartially.

THERE SHOULD BE *NO* DIRECT COMMUNICATIONS CONCERNING AN APPLICATION BETWEEN MEMBERS OF THE PANEL AND APPLICANTS. ALL COMMUNICATIONS OR INQUIRIES REGARDING THE STATUS OF AN APPLICATION SHOULD BE REFERRED TO THE SRA.

Panel members are also bound by the confidentiality of all proprietary parts of the proposals they read under this guidance; no Panelists will disclose or use to their own advantage any data, concept, research protocol, or any other idea included in the applications.

Privacy Act

Under the Privacy Act, applicants may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports, Summary Statements, and reviewers' written comments, if available. Reviewers' written comments and scores, however, are not retained after their substance has been incorporated into Summary Statements or site visit reports.

Panelist Expenses

The Chair's cooperative agreement for the research grant application review provides for a budget from which Panelists are reimbursed for expenses and receive a professional fee. Allowable expenses are professional fees, round trip air or rail transportation, ground transportation, and per diem costs, which can vary according to location. A daily consultant fee of $200 is paid to each non-Government Panelist for each day or fraction of a day spent on a site visit or at a meeting of the Panel.

Panelists make their own transportation arrangements and purchase their own tickets. Travel should be by the most direct route. When air transportation is used, travelers are expected to use less than first-class accommodations, although use of first-class accommodations may be necessary under certain circumstances. In cases where reimbursement is claimed for first-class flights, written justification will be required.

Reimbursement may not be paid for additional costs resulting from indirect routing or stopovers if made for reasons not related to the Panel review trip. Such additional costs should be waived or explained if reimbursement is claimed. Dual compensation from the Government cannot be paid for a trip. If a Panelist provides service for some other activity during the same trip, the charges should be prorated between the two organizations in an appropriate manner, giving the name of the other agency in cases of co-sponsored trips.

Reimbursement forms (Appendix D) are distributed by the SRA during the Panel meetings or site visits. Social Security numbers and home addresses should be included in the spaces provided to ensure prompt reimbursement. The completed reimbursement forms should be mailed to the Chair, not the SRA.

Appendix A

Guidelines for Reviewers' Written Evaluation

Description of Proposed Research

Give a brief statement of objectives, rationale, experimental methods, and expected results.

Critique

Identify strengths and weaknesses in the experimental design. Comment on the originality and creativity of the proposed research, appropriateness and adequacy of the research materials, and the methods to be used. Be as specific and candid as necessary in your assessment.

Investigator(s)

Comment on principal investigator(s) research training, knowledge of pertinent literature, experience, and competence; the probability of completing the work in a competent and timely fashion; the potential of younger scientists to develop an adequate understanding of the problem area in which the work is directed.

Facilities/Equipment

Comment on the availability and/or adequacy of the facilities and equipment proposed for the project. Identify any deficiencies that may interfere with the successful completion of the research.

Budget

Comment on the appropriateness of the budget relative to particular items (e.g., personnel, equipment, travel, etc.). Data on recommended budget adjustments should be enumerated by year and should be as detailed as is practicable.

Recommendation

Make recommendation on the merit of the proposal for EPA funding support (approval, disapproval, or deferral).

Appendix B

Research Materials

The use of certain research materials is subject to satisfactory compliance with relevant Federal regulations, policies, or guidelines. The research materials of concern are: (1) Human Subjects, Derived Material and Data; (2) Laboratory Animals; and (3) Hazardous Research Material and Methods (including recombinant DNA). EPA generally conforms to the regulations, policies and/or guidelines established by the Department of Health and Human Services (DHHS) for the proposed use of these research materials.

Although the grant recipient institution and investigator bear the primary responsibility for the proper use of these research materials, EPA staff and Science Review Panel members must share this responsibility. Proposals should be reviewed as to the adequacy of the applicants' capabilities, resources, and proposed methods for use of these materials and conformance with applicable law and policy. Any concerns or questions of Panel members regarding the proposed use of these research materials must be provided in the "critique" of the Summary Statement. No awards may be made unless EPA has reasonable assurance that the applicant will be in compliance with EPA policy and guidelines and all concerns or questions raised by the Panel have been resolved to the satisfaction of the Research Grants Staff (RGS).

As noted above, EPA conforms to DHHS guidelines for the proposed use of these research materials. Some paraphrased excerpts pertaining to DHHS policy regarding the use of these materials are provided below.

1. Human Subjects, Derived Material, and Data

   Applicants planning or contemplating studies that involve human subjects or derived materials or data that contain personal identifiers or can be linked to personal identifiers are required to submit Form HSS 596 to ensure appropriate institutional review, certification, and compliance with DHHS policy. This policy is based on DHHS Regulation 45 CFR 46, which is available from the Office of Protection from Research Risks, National Institutes of Health, Bethesda, Maryland 20205.

   This regulation provides a systematic means, based on established ethical principles for protecting the rights and welfare of individuals who may be exposed to the possibility of physical, psychological, or social injury while they are participating as subjects in research, development, or related activities. The regulation extends to the human fetus (either in utero or ex utero), the dead, organs, tissues, and body fluids, and graphic, written, or recorded information derived from human sources. It covers activities that present no physical risk to the subjects, but which may create legal risks or exposed subjects to public embarrassment or humiliation through breach of confidentiality or invasion of privacy. The major focus of a project (for example, on

medical procedure) may not be the sole determinant of the types of risks involved or the need for additional protection.

The safeguarding and confidentiality of medical records and other forms of data collected on individuals and groups, the use of such data either by the principal investigator/program director conducting the original research, concurrent uses of the data by other investigators, and the use of the data for research purposes at a later time are considered within the scope of this policy. The regulation requires institutional assurances, including the implementation of procedures for review, and the assignment of responsibilities for adequately protecting the rights and welfare of human subjects. Safeguarding these rights and welfare is, by DHHS policy, primarily the responsibility of the applicant organization. However, institutional review boards, EPA staff, and Science Review Panels share the responsibility for determining the adequacy of the proposed procedures. In particular, the application organization is responsible for ensuring that the activity described in the application and additional information relating to human subject's derived material or data are reviewed and approved by an institutional review board.

2. Laboratory Animals

EPA policy requires that laboratory animals not suffer unnecessary discomfort, pain, or injury. Applicant organizations using animals in project supported with funds from EPA grants are responsible for the proper care and humane treatment of animals. Each organization must assure the EPA in writing that it is committed to following the standards established by the animal welfare acts and by the docuents entitled "Principles for Use of Animals and Guide for the Care" and "Use of Laboratory Animals," which are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20205.

The general intent of these principles can be summarized as follows in two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists.

- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner that avoids any unnecessary discomfort, pain, or injury.

3. Hazardous Research Materials and Methods

The investigator and applicant institution bear primary responsibility for protecting the environment and research personnel from potential damage associated with the use of hazardous research materials such as carcinogenic and infectious agents, radioactive and explosive or flammable materials, and recombinant DNA molecules. When such hazardous materials are to be used in a proposed study, the panel should evaluate the applicant's capability for the safe handling of such materials and their compliance with Federal policy and guidelines.

In recent years there has been particular concern about the safe research use of recombinant DNA molecules. Proposed studies that involve recombinant DNA must comply with the current NIH Guidelines for Research Involving Recombinant DNA Molecules (The Administrative Practices Supplement and announcements of modifications and changes to the *Guidelines* are available from the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Maryland 20205). All research involving recombinant DNA techniques that is supported by EPA must meet the requirements of these NIH *Guidelines*, which were developed in response to the concerns of the scientific and lay communities about the possible effects of recombinant DNA research. Their purpose is to specify practices for the construction and handling of recombinant DNA molecules and organisms or viruses containing recombinant DNA. As defined by the *Guidelines*, "recombinant DNA" corresponds to: (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) DNA molecules that result from the replication of a molecule described in (1).

Several types of studies involving recombinant DNA are exempt from the *Guidelines*; others are prohibited by the *Guidelines*. For the remainder, the applicant organization must establish and implement policies that provide for the safe conduct of the research in full conformity with the *Guidelines*. This responsibility includes establishing an institutional biosafety committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization and to approve those projects that are in conformity with the *Guidelines*.

Appendix C

No Conflict of Interest Form

Reviewers must be excused from participation in the review of a proposal or a review session when there is any potential or possibility of a conflict of interest. A conflict of interest exists when the reviewer has any financial or personal interest in a proposal being considered by his/her review panel. Situations that may constitute a conflict of interest include, but are not limited to, the following:

- The application being considered is from the reviewer's parent institution or one legally a part of that institution.
- The reviewer has some interest, proprietary or otherwise, in the application.
- The reviewer and the application have been related as student or thesis/postdoctoral advisor.
- The reviewer and applicant are known to be close friends or are related.
- The reviewer and applicant have collaborated recently on a research project.
- The reviewer would benefit directly from the project, e.g., as a consultant or paid collaborator.

When, in the opinion of the reviewer, the Science Review Administrator, or the Panel Chair, the appearance or actuality of a conflict of interest emerges, reviewers must be excused from the review panel meeting for as long as is necessary to avoid such circumstances.

I certify that I have read the above statement and that no conflict of interest exists with regard to my review and discussion of EPA assistance applications at this review panel meeting. In the event that a conflict situation should arise, I will notify the Panel Chair accordingly.

Signature: _____

Date: _____

Appendix D

Panelist Reimbursement Form

Statement of Travel			
T/O #:		Date:	
Itinerary	Date/Time Residential:		
	Departure:		
	Return:		
Name	Mailing Address		
SSN			

Date (Day)	Transportation		
	Location	Time	Flight # or Odometer Reading
	LV		
	AR		
	LV		
	AR		
	LV		
	AR		
	LV		
	AR		
	LV		
	AR		
	LV		
	AR		
	LV		
	AR		
	LV		
	AR		

Form Continued on Following Page

Food and	Lodgings	Other Expenses		
		Taxi, Limo, Tolls, Parking, Rental Car, etc. Receipts required for each entry over $25. ITEMIZE		Totals
Breakfast				
Lunch				
Dinner				
Lodging				
Breakfast				
Lunch				
Dinner				
Lodging				
Breakfast				
Lunch				
Dinner				
Lodging				
		Other—(Explain)		

Subtotal	
Travel Advance	
Total Claim	

Remarks:

Professional Fee for _____ Days.

*USGPO: 1985 — 559-111/10779